REMARKS

Claims 7 and 52-55 are under examination and have been rejected.

In amending or canceling claims, Applicant reserves the right to pursue the claims as filed or claims of differing scope in this or future application. In addition, Applicant respectfully submits that no new matter is introduced by any of these amendments and the new claims. Applicant requests reconsideration of the application and the amended claims and examination of the newly presented claims in light of the following remarks.

Objection to Claims

Claim 7 was objected to for use of the acronym "PERV" without the words it stands for. In response, Applicant has canceled claim 7.

Rejection Under 35 U.S.C. §112, First Paragraph

Claim 7 was rejected under section 112, paragraph 1, as containing new matter in that it is directed to a kit whereas the application does not disclose a kit. In response, Applicant has canceled this claim.

Claims 52-56 were rejected under section 112, paragraph 1, as failing to comply with the written description requirement. The rejection is based on disclosures by others that the different PERVs utilize different receptors. In response, Applicant has amended claim 52, and thus the claims dependent therefrom, to recite that the claimed polypeptide binds to PERV-A. In addition, Applicant has canceled claim 56.

The Examiner argues that the specification is not enabling for a polypeptide specifically binding to other PERVs, in addition to PERV-A, or other retroviruses.

The Examiner states, at page 7 (first full paragraph) of the Office Action, that the ordinary artisan would be able to use a polypeptide comprising 85% to 100% (identity to) SEQ ID NO: 14 (or immunogenic fragments thereof), for specific PERV-A binding and that such specific binding does occur (see page 7 of the office action, last full paragraph). Because Applicant has amended claim 52 to recite that the claimed polypeptide binds to PERV-A Applicant believes that this claim now meets the requirements of section 112, paragraph 1, and that the ground of rejection has been overcome.

In light of the amendments which recite a particular distinguishing feature or biologic activity of the polypeptides, the rejection to these claims is now believed to be overcome. Applicant requests reconsideration and withdrawal of rejection 35 U.S.C. §112, first paragraph.

Rejection Under 35 U.S.C. §102

Claims 52-57 were rejected under section 102(a) as anticipated by a sequence alignment of SEQ ID NO: 14 (the human PERV-A receptor) with a sequence disclosed by Isogai et al (1 October 2000, Accession No. Q9NWF4 of the SPTREMBL_21 database), which alignment shows sequence identity of 99.8%.

Applicant notes that these references were cited under 35 U.S.C. 102(a) because they have effective dates less than 1 year prior to the Applicant's own priority date of 20 April 2001.

Applicant acknowledges the Examiner's reference to Ota et al (Accession AAB92492, with date of 26 June 2001), which because of its date is not prior art but that the same sequence is contained in European Patent EP1074617-A2 (which claims SEQ

ID NO: 10589), which is 2537 pages in length, and that the Examiner has determined the sequence alignment between the sequence disclosed in the Ota et al submission and SEQ ID NO: 14 of the present invention to be of 99.8% identity, thus asserting the EP patent as a reference. However, the EP patent has a date of 7 February 2001. Again, this reference would have to be asserted under 102(a) because it is less than 1 year prior to the Applicant's priority date.

In response, Applicant notes that Isogai et al. describe this sequence as a hypothetical 46.3 kilodalton protein (line "DE" in Examiner's "Result 1"). Conversely, Applicants are claiming an isolated polypeptide having definite properties in terms not only of amino acid sequence but ability to bind PERV-A. The Examiner contends that an inherent property in a disclosed protein is sufficient for section 102 purposes but here there is no isolated protein being disclosed – only a hypothetical amino acid sequence. For example, it does not teach whether the initial methionine residue is required or can be removed and does not state if any signal sequence is present or can be removed. In short, it is merely a hypothetical sequence.

Thus, based on the disclosure of Isogai et al, those in the art only know that some place within the human genome there is an open reading frame that, if translated into protein, would produce a protein having the indicated amino acid sequence (based on a reading of the genetic code). Isogai et al does not disclose that they have actually synthesized such a protein, or isolated it from a human, or any other, source.

The Examiner refers to the Isogai hypothetical polypeptide as an "old product" but Applicant reiterates that it is not a "product" at all but just a hypothetical polypeptide. Isogai does not meet the requirements for anticipation because it does not disclose a product having all limitations of the claim. It does not disclose an isolated protein but only a hypothetical sequence and does not disclose a protein having any definite functional character, without which no one is likely to have ever actually prepared such a protein (because they would not know what to do with it).

If Isogai et al is an anticipatory reference then it should be possible for those in the art to go through the human genome (based on data from the human genome project) with a computer and generate the sequence of every hypothetical protein from every identifiable open reading frame and thereby prevent patenting of any isolated proteins, regardless of the difficulty or pitfalls of actually preparing such a protein or learning its properties and function.

Applicant would not be accorded a patent on a hypothetical sequence that exists within the genome but is neither isolated nor shown to have a specific function but rather is entitled to a patent on an isolated polypeptide. It is the isolation that makes the polypeptide patentable, along with a stated use and how to use. Applicant contends that Isogai et al does not disclose the isolated polypeptide of claim 52 but only a hypothetical sequence and therefore fails to meet the limitations of the claim.

The Commissioner is authorized to charge payment of any fees associated with this communication or credit any overpayment to Deposit Account No. 03-0678.

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Respectfully submitted,

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